UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, v. SYBARITIC, INC., a corporation, ANTHONY S. DAFFER, STEVEN J. DAFFER, and RONALD BERGLUND, individuals, Defendants.	)	No. CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunction against Sybaritic, Inc. ("Sybaritic"), a corporation, and Anthony S. Daffer, Steven J. Daffer, and Ronald Berglund, individuals (collectively, "Defendants"), and Defendants, without admitting or denying the allegations in the complaint, having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, and the United States having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301 et. seq.

3. The Complaint alleges that Defendants violate the Act,

21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls use for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice requirements prescribed at 21 C.F.R. Part 820.

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), in that they are Class III devices pursuant to 21 U.S.C. § 360c(f), and there are no approved applications for premarket approval ("PMAs") on file with the FDA as required by 21 U.S.C. § 360e(a), and the devices do not have approved applications for an investigational device exemption under 21 U.S.C. § 360j(g).

5. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices,

as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of 21 U.S.C. § 352(t)(2), in that Defendants have failed to furnish material or information respecting the devices to FDA as required by 21 U.S.C. § 360(i) and the implementing regulations set forth in 21 C.F.R. Part 803.

6. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of 21 U.S.C. § 352(o), in that Defendants have failed to provide notice or other information respecting the devices to FDA as required by 21 U.S.C. § 360(k).

7. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing the devices to become adulterated within the meaning of 21 U.S.C. §§ 351(h) and/or 351(f)(1)(B), as described in paragraphs 3 and 4 above, and misbranded within the meaning of 21 U.S.C. §§ 352(t)(2) and/or 352(o), as described in paragraphs 5 and 6 above, while such devices are held for sale after shipment in interstate commerce.

8. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(q)(1)(B), in that Defendants have failed to furnish notification or other material or information to FDA as required by 21 U.S.C. § 360(i) and the implementing regulations

set forth in 21 C.F.R. Part 803.

9. Upon entry of this Decree, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of the contents of this Decree by personal service or otherwise, are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly designing, manufacturing, processing, packing, repacking, labeling, holding, distributing, importing into or exporting from the United States of America, any device, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality System regulation prescribed in 21 C.F.R. Part 820.

B. Defendants select and retain at their expense an independent person or persons (the "Expert"), to conduct inspections of Defendants' operations and to review Defendants' procedures and methods for designing, manufacturing, processing, packing, repacking, labeling, holding, and distributing devices, to determine whether their methods, facilities, and controls are

operated and administered in conformity with the Act, its implementing regulations, and this Decree. The Expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their immediate families. Defendants shall notify FDA in writing of the identity of the Expert within ten (10) calendar days of retaining such Expert.

C. The Expert shall perform a comprehensive inspection of Defendants' operations and certify in writing to FDA: (1) that he or she has inspected Defendants' facilities, processes, and controls; (2) whether Defendants have corrected all violations set forth in FDA's Inspectional Observations (Forms FDA 483) from all prior FDA inspections since 2004; and (3) based upon this comprehensive inspection, whether Defendants' operations are operated in conformity with the Act, its implementing regulations, and this Decree. The Expert's certification report shall encompass, but not be limited to, an evaluation of the following:

i. Defendants' compliance with 21 U.S.C. §§ 351(h), 360j(f)(1), 352(t)(2), and 352(o), and 21 C.F.R. Parts 803 and 820;

ii. Defendants' procedures for its Corrective and Preventive Action ("CAPA") system including, but not limited to:

analyzing quality data to identify existing and potential causes of nonconforming product and other quality problems; investigating the causes of nonconformities relating to product, processes, and the quality system; identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; verifying or validating corrective and preventative actions to ensure such actions are effective and do not adversely affect the finished device; implementing and recording changes in methods and procedures as needed to correct and prevent quality problems; conducting and documenting adequate failure investigations; and implementing an effective complaint handling system;

iii. Defendants' design control system, including the design change control process; and

iv. Defendants procedures to adequately control received or purchased products to verify conformance to product specifications.

D. Defendants report to FDA in writing the actions that they have taken to: (1) correct all violations brought to Defendants' attention by the Expert and/or set forth in FDA's Inspectional Observations from all prior FDA inspections since 2004; and (2) ensure that the methods used in, and the facilities and controls used for designing, manufacturing, processing, packing, repacking, labeling, holding, and distributing devices

are operated and administered and will be continuously operated and administered in conformity with the Act, its implementing regulations, and this Decree.

E. Within twenty (20) calendar days of receipt of the report under paragraph 9(D), FDA, in its discretion and without prior notice, will commence an inspection of Defendants' operations to determine whether the requirements of this Decree have been met, and whether Defendants' operations are otherwise operated in conformity with current good manufacturing practice, the Act, and its implementing regulations.

F. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 9(A)-(E) of this Decree.

G. Notwithstanding the foregoing, Defendants may continue to service and repair their devices already in distribution so long as they maintain records documenting the number of devices serviced, including serial and model numbers, and the location of the facilities where the devices are returned, and provide copies of such documentation to FDA upon request.

H. The terms of paragraph 9 shall not apply to any device manufactured, processed, packaged, labeled, held for sale, or introduced into interstate commerce solely for export from the United States, provided that the applicable requirements of 21

U.S.C. § 381(e) have been satisfied with respect to any such device.

10. Before Defendants may commence designing, manufacturing, or distributing any device, they shall first notify FDA in writing of their intent to do so, and shall demonstrate to FDA that the device is either: (a) the subject an approved application for premarket approval pursuant to 21 U.S.C. § 360e(a); (b) the subject of a cleared premarket notification pursuant to 21 U.S.C. § 360(k); or (c) is exempt from the premarket approval/clearance requirements. Defendants shall not commence distributing any device prior to receiving written notification from FDA that the device appears to be in compliance with this paragraph. FDA will provide such notification within a reasonable period of time. In no circumstances may FDA's silence be construed as a substitute for written notification.

11. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise, are permanently enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that violates the Act, 21 U.S.C. §§ 331 et seq.

12. After Defendants have complied with paragraphs 9(A)-(D) and FDA has notified Defendants in writing pursuant to paragraph 9(F), Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense to conduct audit inspections of Defendants' operations not less than once every six (6) months for a period of one (1) year and not less than once every twelve (12) months for a period of three (3) years thereafter, for a total of four (4) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to Defendants' officers or employees or their immediate families. The Auditor may be the same person or persons described as the Expert in paragraph 9(B).

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants' operations are operated and administered in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and

FDA by courier service or overnight delivery service, no later than twenty (20) calendar days after the date the audit inspections are completed. If any Audit Reports identify any deviations from the Act, its implementing regulations, and/or this Decree, FDA may, in its discretion, require that the four (4) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty (30) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. That Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved Correction Schedule. Within thirty (30) calendar days of

Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observation(s). Within five (5) calendar days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

13. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analysis of samples, a report or data prepared or submitted by Defendants, the Expert, or the Auditor pursuant to this Decree, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions. Such actions may include, but are not limited to, the following:

A. Cease designing, manufacturing, processing, packing, repacking, labeling, holding, storing, distributing, installing, servicing, importing and/or exporting devices;

B. Revise, modify, or expand any report(s) prepared

pursuant to the Decree;

C. Submit additional notifications, reports, or any other materials or information to FDA;

D. Recall, at Defendants' sole expense, adulterated or misbranded devices or components therein manufactured, distributed, and/or sold by Defendants or that are under the custody and control of Defendants' agents, distributors, customers, or consumers;

E. Issue a safety alert, public health advisory and/or press release; and/or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with Act, its implementing regulations, and this Decree.

14. The following process and procedures shall apply when FDA issues an order under paragraph 13, except as provided in subparagraph (D) below:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's

order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as the Agency deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order while the matter is before the Court and unless and until the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 25 of this Decree.

D. The process and procedures set forth in paragraph 14(A)-(C) shall not apply to any order issued pursuant to

paragraph 13 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall, upon receipt of such an order, immediately and fully comply with the terms of that order. Should the Defendants seek to challenge any such order, they may petition this Court for relief.

15. Any cessation of operations described in paragraphs 13-14 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraphs 13-14 shall be borne by Defendants at the rates specified in paragraph 17.

16. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' operations and, without prior notice, take any other measures necessary to monitor and to ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted: access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants' materials and products, containers, and labeling; and to examine and copy all

records relating to the design, receipt, manufacture, processing, packing, labeling, holding, and distribution of any and all devices. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

17. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $85.49 per hour and fraction thereof per representative for inspection work; $ 102.49 per hour or fraction thereof per representative for analytical or review work; $0.55 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of

the court.

18. Within five (5) calendar days of the entry of this Decree, Defendants shall post a copy of this Decree in the employee common areas at all facilities where Defendants' employees are located and on Defendant Sybaritic's intranet Website in such a manner to ensure that it will be viewed by such employees. Defendants shall ensure that the Decree remains posted in its employee common areas and on its intranet Website for as long as the Decree remains in effect.

19. Within five (5) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of its directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), and all parties involved in the design, manufacture and/or distribution of Defendants' devices (hereinafter, collectively referred to as "Associated Persons"). Within twenty (20) calendar days of the entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who have received a copy of this Decree

pursuant to this paragraph and attaching copies of the executed certified mail return receipts.

20. In the event that Defendants become associated, at any time after the entry of this Decree, with new Associated Person(s), Defendants shall within ten (10) calendar days of the commencement of such association: (a) provide a copy of this Decree to each such Associated Person(s) by personal service or certified mail (restricted delivery, return receipt requested); and (b) provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who received a copy of this Decree pursuant to this paragraph, and attaching copies of the executed certified mail return receipts.

21. Defendants shall notify the District Director, FDA Minneapolis District Office, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the corporate structure of Defendant Sybaritic or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may significantly affect compliance with this Decree. Defendants shall provide a copy of this Decree to any

potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

22. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be addressed to the District Director, FDA Minneapolis District Office, 250 Marquette Avenue, Suite 600, Minneapolis, Minnesota 55401.

23. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on written notice of the United States in this proceeding, Defendants shall pay to the United States of America the sum of fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues and an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree.

24. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and

administrative court costs relating to such contempt proceedings.

25. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. When contested by Defendants, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

26. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

So ordered the 4th day of January, 2010.

UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree:

For Defendants:

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Sybaritic, Inc., as its Chief
Executive Officer

For Plaintiffs:

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Assistant Attorney General

B. TODD JONES
United States Attorney

STEVEN J. DAFFER
Individually and on behalf of Sybaritic, Inc., as its Owner and Chairman

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